SECTION ONE

EXECUTIVE SUMMARY

This economic analysis (EA) examines compliance costs and economic impacts resulting from the U.S. Environmental Protection Agency's (EPA's) Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry Point Source Category, hereinafter known as the Final Pharmaceutical Industry Effluent Guidelines. It also investigates the costs and impacts associated with an air rule requiring Maximum Achievable Control Technology (MACT) to control air emissions, both separately and together with the Final Pharmaceutical Industry Effluent Guidelines. The EA estimates the economic effects of compliance with both final rules in terms of total aggregate annualized costs of compliance, facility closures, impacts on firms (likelihood of bankruptcy and effects on profit margins), and impacts on new sources. The EA also investigates secondary impacts on employment and communities, foreign trade, specific demographic groups, and environmental justice. This report includes a Final Regulatory Flexibility Analysis (FRFA) detailing the impacts on small businesses within the pharmaceutical industry to meet the requirements of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). Finally, the EA presents a cost-benefit analysis to meet the requirements of Executive Order 12866 and the Unfunded Mandates Reform Act.

1.1 OVERVIEW

The remainder of this executive summary section follows the general outline of the EA. Section 1.2 summarizes the primary data sources used for the EA, and Section 1.3 briefly profiles the pharmaceutical industry. Section 1.4 presents an overview of the methodologies used in the EA, focusing on the cost annualization model. Section 1.5 presents the facility-level analysis (closure analysis) and the analysis of impacts on new sources. Section 1.6 presents firm-level impacts in terms of likelihood of bankruptcy, while Section 1.7 briefly summarizes employment impacts. Section 1.8 discusses additional secondary impacts on foreign trade, profitability, specific demographic groups, and environmental justice. Section 1.9 summarizes the results of the FRFA, and Section 1.10 presents the results of the cost-benefit analysis.

1.2 DATA SOURCES

The primary data source used in the EA is the survey of the affected subcategories of the pharmaceutical industry. This survey was conducted under the authority of Section 308 of the Clean Water Act and is referred to in this report as the Section 308 Survey. Through this survey, EPA obtained detailed technical and financial information from a sample of pharmaceutical establishments that potentially will be affected by the Final Pharmaceutical Industry Effluent Guidelines. The industry was stratified into the following five groups, based on type of operations conducted: (A) fermentation, (B) biological and natural extraction, (C) chemical synthesis, (D) formulation and mixing/compounding, and (E) research. EPA censused the facilities in most of these categories, for a total of 202 facilities. EPA sampled 42 facilities, representing 84 facilities nationwide, in the following categories: stand-alone facilities in Group D that use solvents and discharge indirectly, and Group D facilities with onsite research facilities (i.e., group D/E) that use solvents and discharge indirectly.

EPA relies on cost data presented in the *Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Point Source Category* for capital and operating and maintenance (O&M) costs of compliance. For profiling, EPA also relies on data from the U.S. Department of Commerce to supplement Section 308 Survey data. Commerce collects a wide range of data, such as number of establishments, number of employees, volume of shipments, exports, imports, value added, apparent consumption, and manufacturing costs. Other data sources used include those published by the U.S. Food and Drug Administration (FDA), the Bureau of Labor Statistics (BLS), the Pharmaceutical Research and Manufacturers of America (PhRMA), among others, cited where referenced in this report.

1.3 PROFILE OF THE PHARMACEUTICAL INDUSTRY

More than 110,000 pharmaceutical products are currently on the market. These products can be divided into three categories: new drugs (patented, branded drugs); generic drugs (equivalent versions of previously patented drugs), and over-the-counter (OTC) drugs (available without a prescription). Drugs are manufactured using an array of complex batch-type processes and technologies that occur in three main stages: research and development (R&D); fermentation, extraction, and chemical synthesis, which covers the

conversion of organic and chemical substances into bulk active ingredients; and formulation, which refers to the combining of bulk active ingredients with other substances to produce proper dosages.

1.3.1 Facility, Owner Company, and Parent Company Characteristics

According to U.S. Department of Commerce data, 1,343 facilities involved in pharmaceutical production existed in 1990. These facilities employed 194,000 people. Smaller facilities (i.e., those with less than 100 employees) dominate the pharmaceutical industry, although a higher percentage of facilities in the pharmaceutical industry have more than 250 employees than in the manufacturing sector overall. EPA estimates that approximately 286 of the 1,343 pharmaceutical facilities discharge wastewater either directly or indirectly and might be affected by the Final Pharmaceutical Industry Effluent Guidelines. The Section 308 Survey obtained data from 244 of these establishments.

U.S. Department of Commerce data indicate that the value of shipments for the drug industry were $70.0 billion in 1995 ($1990) ($86.2 billion, $1997).[1] In real terms, growth in the industry has averaged 2 to 4 percent annually. The Section 308 Survey data indicate that pharmaceutical facility revenues average approximately $100 million ($123 million, $1997) per facility per year, while average revenues for owner companies are approximately $600 million ($739 million, $1997) per year. The U.S. pharmaceutical industry also has consistently maintained a positive balance of trade, with a trade surplus of $961 million in 1991($1.183 billion, $1997). According to the Section 308 Survey, the mean pharmaceutical export rate for sample facilities was 8.8 percent in 1990.

According to the Section 308 Survey, manufacturing costs for the pharmaceutical industry from 1988 to 1990 rose from $7.4 billion to $9.6 billion ($9.1 billion to $11.8 billion, $1997) at the facility level, from $58.7 billion to $63.8 billion ($72.3 billion to $78.6 billion, $1997) at the owner-company level, and from $149.1 billion to $177.3 billion ($183.6 billion to $218.3 billion, $1997) at the parent company level. In addition, the research and development expenditures for the pharmaceutical industry are more than 16 percent

[1] Costs and benefits in the EA are reported in 1990 dollars. This executive summary reports costs both in 1990 dollars and 1997 dollars. Costs and benefits have been inflated using *Engineering News Record's* construction cost index, March, 1998. Costs and benefits are inflated using the following method: 1997 CCI/1990 CCI = 5,826/4,732 = 1.23119.

of sales, one of the highest proportions for any U.S. industry, while promotional expenditures are approximately 22 percent of the industry's revenues. Overall, the profitability of the industry appears higher than average for U.S. industries as a whole.

1.3.2 Industry Structure and the Pharmaceutical Market

Although the number of pharmaceutical facilities has grown over the last several decades, it is likely that competition would have been greater if high R&D costs, FDA regulations, and other factors did not serve as barriers to entry into the industry. Reflecting these barriers, concentration ratios in some portions of the industry are quite high, although among others, the concentration ratios are lower. Interestingly, exit and entry rates in many drug markets are high. There also is some indication that pharmaceutical companies are vertically integrated. These factors all affect entry of new firms into the pharmaceutical market.

Demand conditions vary significantly among specific drug markets. In the prescription drug market, demand is complicated by the role of health care providers and the presence of health insurance, which reduce the competitive nature of the market. The lack of price sensitivity among consumers, however, is partly offset by increasing sensitivity among insurers. Demand for OTC drugs, on the other hand, conforms more readily to standard models of consumer demand.

The degree of substitutability among pharmaceuticals varies. Patented drugs in the United States enjoy ostensible protection from bioequivalent drugs for a number of years, which can limit direct substitutability. The increase in generic drugs, however, increases substitutability once the patent for a drug expires. For OTC drugs, the market is much like other competitive commodity markets, with a high degree of substitutability causing demand to be relatively sensitive to price changes. In addition, pharmaceuticals are not a very close substitute for most other forms of medical treatments, although they might act as complements.

These factors tend to indicate a relative price inelasticity for pharmaceuticals as a whole. Because regulatory costs associated with the Final Pharmaceutical Industry Effluent Guidelines can affect a large portion of the pharmaceutical industry, the industry as a whole might be able to pass through regulatory costs to consumers in the form of higher drug prices. Individual companies, however, may have less latitude in

passing through costs, although many specific companies do appear to have sufficient market power to pass through regulatory costs. Throughout most of the EA, however, EPA uses the conservative assumption that the affected industry cannot pass through compliance costs to consumers.

1.4 ECONOMIC IMPACT ANALYSIS METHODOLOGY OVERVIEW AND COMPLIANCE COST ANALYSIS

EPA has developed a number of regulatory options, which are analyzed in this EA. These options are divided into those for direct dischargers and those for indirect dischargers. In addition, A and C industry subcategories (representing facilities that use fermentation or biological and chemical synthesis) are distinguished from B and D industry subcategories (representing facilities that use biological and natural extractive processes or that are formulators of pharmaceutical products). Table 1-1 describes these options and provides an option name that corresponds with the option name used in the Development Document and a shortened name that will be used in the EA.

EPA's selected options are as follows:

- A/C Directs: BPT-A/C and BAT-A/C; NSPS-A/C for new sources
- B/D Directs: BPT-B/D and the no-action BAT alternative (not shown in Table 1-1); NSPS no-action alternative (not shown in Table 1-1) for new sources
- A/C Indirects: PSES-A/C; PSNS-A/C for new sources
- B/D Indirects: PSES-B/D; PSNS-B/D for new sources.

Note that the selected NSPS and PSNS options are identical to those selected for existing sources.

Section Four presents the overview of the EA methodology and describes the principal economic and financial models used. Figure 1-1 shows how these principal models (the cost annualization model, the facility closure model, and the owner company model) interact.

The cost annualization model estimates the annual compliance costs to the facility of new pollution control equipment and operations. This model provides the data necessary for the facility- and firm-level

Table 1-1

Summary of Regulatory Options Considered In Economic Analysis[a]

Regulation	Short Option Description for EA Only	Option	Type of Treatment
BPT	BPT-A/C	Revise COD and modify cyanide	Advanced biological treatment
	BPT-B/D	Revise COD and withdraw cyanide	Advanced biological treatment
BAT	BAT-A/C	Add organics, ammonia, and COD and modify cyanide	Advanced biological treatment with nitrification
	BAT-B/D	Add COD and withdraw cyanide	Advanced biological treatment
NSPS	NSPS-A/C	Promulgated level of BPT/BAT control	Advanced biological treatment with nitrification
	NSPS-B/D	Promulgated level of BPT/BAT control	Advanced biological treatment
PSES	PSES-A/C	Add organics, ammonia,and modify cyanide	In-plant steam stripping for organic compounds and ammonia
	PSES-B/D	Add organics and withdraw cyanide	In-plant steam stripping for organic compounds
PSNS	PSNS-A/C	Add organics, ammonia, and modify cyanide	In-plant steam stripping for organic compounds and ammonia
	PSNS-B/D	Add organics and withdraw cyanide	In-plant steam stripping for organic compounds

[a] Many other options were considered and rejected for reasons other than economic achievability. See EPA's Development Document. Also, no-action options are included for all regulations. BCT is not analyzed in the EA. See the Development Document.

Source: U.S. EPA, 1998. *Technical Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category*.

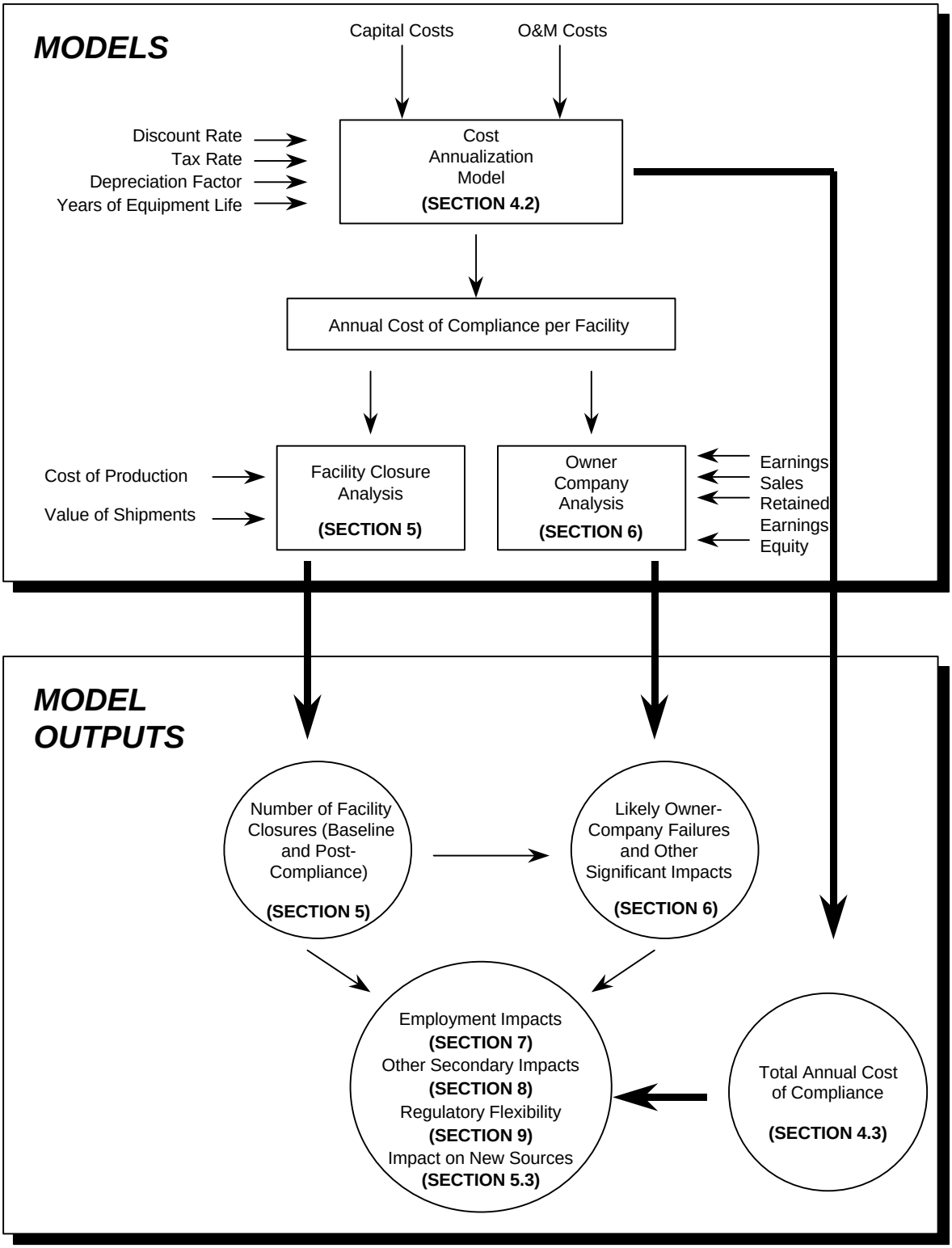

Figure 1-1. Interrelationship of EA methodology components.

analysis. Annualizing costs is a technique that allocates the capital investment over the lifetime of the equipment, incorporates a cost-of-capital factor to address the costs associated with raising or borrowing money for the investment, computes tax-reducing effects of expenditures (e.g., depreciation allowances on corporate income tax), and includes annual O&M costs. The resulting annualized cost represents the average annual payment that a given company will need to make to upgrade its facility.

The annualized costs for each of the selected options for each subcategory are presented in Table 1-2. As the table shows, costs of the options range from $0.2 million to $23.4 million ($1990) ($0.3 million to $28.8 million, $1997), with the selected options ranging from $0.7 million ($0.9 million, $1997) (for B/D directs; cost of BPT only) to $23.4 million ($28.8 million, $1997) for A/C indirects.[2] Each subcategory also has a no-action option. These no-action options are not presented here because they are associated with zero costs. Average costs per facility range from $16,000 to $266,000 ($1990) ($19,000 to $327,000, $1997) among the selected options. Total costs of all selected options is $32.0 million ($1990) ($39.4 million, $1997).

Table 1-3 presents the sum of the selected options, as well as compliance costs for MACT standards requirements (which are annualized using the same cost annualization model and assumptions).[3] As the table shows, the total cost of the selected options for the Final Pharmaceutical Effluent Guidelines is $32.0 million ($1990) ($39.4 million, $1997). With MACT standards wastewater emission control costs included, the water-related cost of the two rules is $37.8 million ($1990) ($46.6 million, $1997). Total cost of both rules together (for facilities in the effluent guidelines analysis only) is $58.3 million ($1990) ($71.8 million, $1997). Total cost of both rules, including MACT standards costs for facilities not covered by the Final Pharmaceutical Industry Effluent Guidelines, is $63.0 million ($1990) ($77.5 million, $1997).

[3] The MACT standards costs are divided into two major components for the purposes of the EA: wastewater emission control costs and total MACT standards costs.

Table 1-2

Annualized Posttax Costs of Compliance with Final Pharmaceutical Industry Effluent Guidelines

Option	Capital Costs		O&M Costs		Annualized Compliance Costs		Facilities Incurring Costs **	Average Costs per Facility ***	
	$1990	$1997	$1990	$1997	$1990	$1997		$1990	$1997
Direct Discharge									
BPT-A/C	$2,422,402	$2,982,437	$1,825,253	$2,247,233	$1,275,930	$1,570,912	24	$53,164	$65,455
BPT-B/D	$1,785,772	$2,198,625	$966,864	$1,190,393	$715,893	$881,400	14	$51,135	$62,957
BAT-A/C	$5,569,135	$6,856,663	$2,423,726	$2,984,067	$1,881,579	$2,316,582	24	$78,399	$96,524
Indirect Discharge									
PSES-A/C	$80,864,749	$99,559,870	$28,597,244	$35,208,641	$23,407,105	$28,818,593	88	$265,990	$327,484
PSES-B/D	$22,067,126	$27,168,825	$5,010,342	$6,168,683	$4,729,914	$5,823,423	153	$30,914	$38,062
All Facilities									
Total Selected Options	$112,709,184	$138,766,420	$38,823,429	$47,799,017	$32,010,421	$39,410,911	279	$114,733	$141,258

* All subcategories have a no-action option; the no-action options are not presented here, since costs for those options are zero.
** The total number of facilities incurring costs includes all facilities except for seven zero discharge facilities.
*** Over number of facilities that incur costs.

Table 1-3

Cost of Selected Options and MACT Standards Costs

Cost Category	Capital Costs		O&M Costs		Annualized Compliance Costs		Facilities Incurring Costs *	Average Costs per Facility **	
	$1990	$1997	$1990	$1997	$1990	$1997		$1990	$1997
Selected effluent guidelines option costs	$112,709,184	$138,766,420	$38,823,429	$47,799,017	$32,010,421	$39,410,911	279	$114,733	$141,258
MACT standards costs (wastewater emission controls)	$30,907,772	$38,053,339	$5,644,605	$6,949,581	$5,810,120	$7,153,362	20	$290,506	$357,668
Total MACT for effluent guidelines analysis	$102,822,547	$126,594,091	$30,535,434	$37,594,921	$26,305,357	$32,386,892	71	$370,498	$456,153
Total MACT standards costs, all facilities	$120,263,588	$148,067,327	$36,007,268	44,331,788	$30,940,806	$38,094,011	NA	NA	NA
Selected effluent guidelines options and MACT standards wastewater costs	$143,616,956	$176,819,760	$44,468,034	$54,748,598	$37,820,541	$46,564,272	279	$135,557	$166,897
Selected effluent guidelines options and MACT standards total costs (effluent guidelines facilities only)	$215,531,731	$265,360,512	$69,358,862	$85,393,938	$58,315,778	$71,797,803	279	$209,017	$257,340
Selected effluent guidelines options and MACT standards total costs (all facilities) ***	$232,972,772	$286,833,747	$74,830,697	$92,130,805	$62,951,227	$77,504,922	NA	NA	NA

* The total number of facilities incurring costs includes all facilities except for seven zero discharge facilities.
** Over facilities that incur costs.
*** Total includes MACT standards costs for some facilities not in the effluent guidelines analysis; the average is calculated only over facilities in the effluent guidelines analysis.

1.5 ANALYSIS OF FACILITY-LEVEL IMPACTS

The facilities in the facility-level analysis are those that are owned by multifacility firms. Impacts on single-facility firms are analyzed in the firm-level analysis to avoid double counting impacts (these firms can be failures only, or failures and closures). Included in this analysis, but not directly analyzed, are 65 facilities (representing 72 facilities nationwide) that certified that the rule would have no impact on the facility. The model places these 72 facilities automatically into the "no closure" category.

Facility closures are determined if the estimated present value of posttax operating earnings of these nonindependent facilities are positive in the baseline analysis but postcompliance are shown to be zero or negative (facilities whose earnings are negative in the baseline are investigated further in the firm-level analysis). The analysis was run for three baseline conditions. In Baseline 1, EPA assumes that the MACT standards costs are not in effect. EPA adjusts Baseline 1 to create Baseline 2 by incorporating the change in posttax earnings associated with the MACT standards wastewater emission control costs. The change in posttax earnings is generated by the cost annualization model. The same procedure is also used to incorporate the change posttax earnings associated with total MACT standards costs to create Baseline 3. Baseline closures are assessed for all three baselines. Costs of compliance with the Final Pharmaceutical Industry Effluent Guidelines are then used to adjust each baseline's earnings to create a postcompliance picture of posttax earnings at the facilities in the facility-level analysis.

Under Baseline 1, 18 facilities out of 206 nonindependent and certifying facilities (8.7 percent) are estimated to close regardless of regulatory requirements (but are investigated further at the firm level). No additional facilities close under Baseline 2 or 3 (thus MACT standards costs by themselves will not have a major impact on the facilities analyzed in this EA).

Postcompliance, under Baselines 1 and 2, no facilities are expected to close as a result of the Final Pharmaceutical Industry Effluent Guidelines. Only in Baseline 3 (with all MACT standards costs considered) does one facility (an A/C indirect discharger) close under the selected options.

For new sources, the selected options are equivalent to the selected options for existing sources. Because the costs for designing pollution control technologies are generally no more expensive than and are usually less expensive than retrofitting pollution control technologies, costs for new facilities will be no more

expensive than costs for existing facilities. Because EPA has shown that the requirements for existing sources are economically achievable, they should be economically achievable for new sources. Furthermore, since the requirements for new sources will not be more expensive than those for existing sources, the rule will not pose a barrier to entry for new sources. Additionally, EPA investigated whether impacts from the effluent guidelines rule (with and without MACT standards costs included) might contribute to firms locating new facilities in foreign countries. EPA determined that the median percentage of the capital costs of compliance (including MACT standards costs) to build a new facility would be negligible (0.21 percent of estimated startup costs at newer surveyed facilities). Thus compliance costs associated with Final Pharmaceutical Industry Effluent Guidelines and/or the MACT standards rule are unlikely to be a major impetus to locating new facilities outside the United States.

1.6 ANALYSIS OF FIRM-LEVEL IMPACTS

EPA investigated the effects of regulatory compliance on owner companies in the firm-level analysis. This analysis uses the Altman's Z equation, which is a multidiscriminant equation that allows a variety of financial ratios to be assessed, weighted by their ability to predict bankruptcy. This equation can be used to predict three outcomes; "bankruptcy likely," "indeterminate," or "bankruptcy unlikely." As in the facility-level analysis, EPA develops three baselines against which to judge the impacts of the Final Pharmaceutical Industry Effluent Guidelines. In each baseline, baseline failures are removed from the analysis, so that the results of the postcompliance analysis show the impacts of the effluent guidelines (and MACT standards costs, where applicable) incremental to firm failures that are estimated to occur regardless of whether the two rules are ever promulgated.

EPA determined that under Baseline 1 (no MACT standards costs considered) 18 firms are likely to fail before the effects of any regulatory costs are considered. These 18 firms are 9.6 percent of the total number of firms in the analysis. One additional firm fails under the assumptions of Baseline 2 (MACT wastewater emission control costs included), and two additional firms fail (compared with Baseline 1) under the assumptions of Baseline 3 (total MACT standards costs included).

Postcompliance compared to Baseline 1, EPA estimates that four firms potentially face bankruptcy (or loss of independent status), or 2.4 percent of all firms. One of these same firms fails under the initial

Baseline 2 assumptions, so does not appear as a postcompliance failure under Baseline 2. Two of these firms fail under the initial Baseline 3 assumptions, so they also do not appear as postcompliance failures under Baseline 3. To be conservative, EPA assumes the four firm failures are attributable to the Final Pharmaceutical Industry Effluent Guidelines, regardless of baseline. Out of the four firm failures projected to occur, only one is expected to result in both a firm failure and a facility closure. The other three firms will incur substantial impacts up to and including firm failure (although in reality they might not fail, but instead might be forced to sell their facilities). Furthermore, all facilities projected to close in the baseline facility closure analysis can be supported by their firms postcompliance without significant impact on these firms.

1.7 NATIONAL AND REGIONAL EMPLOYMENT IMPACTS AND TOTAL OUTPUT LOSSES

This section discusses impacts on national-level and industry-level output and employment from the Final Pharmaceutical Industry Effluent Guidelines (and MACT standards rule). Output is measured in terms of revenues, and under the assumption that industry cannot pass through compliance costs to consumers, the worst-case output loss to the pharmaceutical industry is equal to the pretax costs of compliance. The output losses occurring in the pharmaceutical industry (direct effects) affect input industries, which are industries that provide inputs (e.g., raw chemicals) to the pharmaceutical industry. These effects are known as indirect effects. The direct output losses also affect consumption, as workers lose jobs or work fewer hours and their households reduce purchases of goods and services. These effects are called induced effects. Thus a dollar of output lost in the pharmaceutical industry can also result in additional dollars lost in the U.S. economy as a whole through indirect and induced effects. EPA calculates these additional losses at the national level using input-output multipliers developed by the U.S. Department of Commerce's Bureau of Economic Analysis (BEA).

In addition to output losses, EPA calculates national-level output gains based on output gains in pollution control industries. These industries receive revenues from the pharmaceutical industry for pollution control equipment and operations. Using BEA multipliers, the Agency calculates the subsequent effect of these gains on the pollution control industries' input industries and consumption (i.e., indirect and induced effects). By comparing national-level output losses and gains, EPA develops a *net* national-level output loss or gain.

Because output effects and employment are linked in input-output analysis, EPA calculates employment losses based on output effects using BEA's final demand and direct effect multipliers. EPA uses final demand employment multipliers to compute the total number of jobs lost (including direct, indirect, and induced job losses) given the total loss of output in millions of dollars in the pharmaceutical industry and uses direct effect multipliers to compute the total number of job losses occurring just in the pharmaceutical industry (direct losses), given the total jobs lost nationwide (which include direct, indirect, and induced losses).

EPA also computes employment gains on the basis of output gains in pollution control industries. EPA compares the employment losses and gains to estimate a net gain or loss in employment both at the national level and in the pharmaceutical industry alone (some gains will occur in the pharmaceutical industry since labor to operate pollution control equipment is required).

EPA estimates that at the national level, output gains will exceed output losses. EPA determines a net output gain of about $18.3 million ($1990) ($22.5 million, $1997) as a result of the effluent guidelines. Net output gains for the combined rulemakings (including MACT standards for facilities in the effluent guidelines analysis only) will total $33.8 million ($1990) ($41.6 million, $1997). EPA also determines that employment gains will exceed employment losses at the national level. The net gain in national-level employment as a result of the effluent guidelines alone will total 218 full-time equivalents (a full-time equivalent, or FTE, equals 2,080 hours per year of labor), and net employment gains for the combined rulemakings (including MACT standards for facilities in the effluent guidelines analysis only) will total 407 FTEs.

Despite net employment gains at the national level, EPA calculates that losses will exceed gains in the pharmaceutical industry. The direct losses computed on the basis of output losses (and net of gains in employment in the industry due to the need to operate the pollution control equipment) are nearly the same as the closure/failure losses (which are estimated to total 139 FTEs). Output-based losses total 138 FTEs, or 0.1 percent of pharmaceutical employment in the analysis. With MACT standards costs for facilities included in the effluent guidelines analysis, net direct employment losses will total 254 FTEs, or 0.1 percent of employment.

Because output-based employment losses are greater than closure/failure employment losses, nonclosing facilities might experience some small reductions in labor hours and production over time that are additional to the losses of labor hours and production associated with facilities that close or fail (assuming a worst-case scenario where no costs can be passed through to consumers).

The losses in employment due to closures/failures will have a negligible impact on individual communities. No community is expected to experience a change in its unemployment rate exceeding 0.4 percent.

1.8 OTHER SECONDARY IMPACTS

In this section of the report, EPA investigates five separate types of impacts: impacts on trade (including impacts on profitability that might encourage firms to relocate themselves or facilities to foreign countries), impacts on inflation, impacts on POTWs through reductions in revenues related to reductions in loadings, particularly in biological oxygen demand (BOD), impacts on distributional equity through potential product price increases, and impacts on environmental justice (comparing who ultimately pays for a regulation compared to who ultimately benefits from it).

To investigate trade impacts, EPA determined the foreign shipments of closing facilities (determined in the facility-level analysis), under the assumption that lost production might be supplied by foreign sources. The facilities estimated to close, however, do not have any foreign shipments, thus their closing will have no impact on the balance of payments.

EPA then investigated impacts of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule on profit margins (measured as posttax EBIT divided by revenues). Only eight firms (nine firms if MACT standards costs are considered as well) are expected to experience significant changes in profit margins and these firms are considered the least likely to relocate their facilities to foreign countries. These firms tend to be small, and, generally, they are unlikely to have experience in international locations. The transaction costs of learning how to operate in foreign countries, along with the expense of relocating, are likely to be prohibitively expensive for these firms. Thus EPA has determined that even under the combined

effect of the two rules, firms are unlikely to relocate to foreign countries to escape the impacts on profitability induced by the two rules.

The rules, together or separately, will have no major impact on inflation, as the costs of the two rules are at most only 0.001 percent of gross domestic product (GDP).

EPA also expects that impacts on POTWs will be minimal. The Agency expects that the reduction in the BOD discharged to POTWs as the result of compliance with PSES for these pollutants will be minimal. As a result, EPA believes that any reduction in revenue to POTWs that charge industrial users subject to the PSES will be insignificant. Even if BOD loads to POTWs were to drop substantially, there are a number of mitigating factors to consider. First, EPA estimates that very few POTWs receive a large portion of their flow from pharmaceutical facilities. Second, the way in which POTWs set their fees must be considered. Many POTWs price their services on the basis of total flow alone, and others on the basis of total flow but only secondarily on loads or concentrations. A drop in the load to a POTW thus might not trigger any reduction in revenues. Third, even if a POTW receives a large portion of flow from affected pharmaceutical facilities, and it sets fees on the basis of pollutant loadings or concentrations rather than raw volume, effects on both revenues and costs must be considered. With smaller loads or lower concentrations of pollutants, POTWs' costs can also be reduced. Finally if any revenue shortfall were to occur, POTWs might raise rates very slightly and thus cost increases would be spread out over a large number of users, further diluting any impacts.

The Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule, together or separately, will have no major distributional impacts. Compliance costs are generally a very small percentage of baseline pharmaceutical operating costs, thus any cost increases are likely to be very small and are not likely to have any major effect on any one group of consumers. EPA did investigate the products at several firms where, if 100 percent of compliance costs were passed through to consumers, a significant price increase might occur (a total of 9 firms showed the potential for price increases of 10 percent or more on their products). These products might tend to be used more by several groups of consumers that in some cases are also more sensitive to price increases (since some groups are more likely to be uninsured). The potentially disproportionate users include children, young adult women, and the elderly. However, given the limited number of products involved (40 out of more than 110,000 pharmaceutical products), EPA expects that impacts on distributional equity will be minimal.

Impacts on environmental justice also should be minimal. As noted above, any price increases on drugs will be very small and impacts on disadvantaged groups such as the poor and certain minority groups will be minimal. Furthermore, many of these groups will benefit from the effluent guidelines final rule. A large portion of the affected facilities are located in urban areas where poor or minority populations tend to be high. Although everyone benefits, it is these populations that will likely benefit the most from the cleaner water resulting from both rules.

1.9 FINAL REGULATORY FLEXIBILITY ANALYSIS

EPA estimates that a maximum of 145 out of 190 (76 percent) pharmaceutical firms subject to the rule might be classified as small under SBA definitions. Small firms are defined in 13CFR Part 121 either by their employment size or by their revenues. The relevant portion of the pharmaceutical industry is defined as small using an employment size of either 500 or 750, depending on the 4-digit SIC designation. For simplicity, and as done in the Initial Regulatory Flexibility Analysis (IRFA) at proposal, this FRFA designates all pharmaceutical firms as small if they employ fewer than 750 persons.

EPA undertook an initial analysis as suggested by SBREFA guidance issued by the Agency. This initial analysis, the revenue test, determines how many and the percentage of small firms whose compliance costs are more than 1 percent and more than 3 percent of revenues. If the number or percentage of firms exceeding these benchmarks is low (for example, if fewer than 100 firms incur costs that are greater than 1 percent of annual revenues and if fewer than 100 firms incur costs that exceed 3 percent of annual revenues), the rule is considered to meet qualifications allowing the EPA Administrator to certify the rule as having no significant impact on a substantial number of small entities. In the case of the Final Pharmaceutical Effluent Guidelines, EPA determined that only 4 small firms or 3.2 percent of all small firms that could be analyzed will incur annual compliance costs that are greater than 1 percent of annual revenues and no firms will incur costs exceeding 3 percent of annual revenues. Even when MACT Baseline 3 costs are added in, only 6 firms (4.8 percent) will incur annual compliance costs that are greater than 1 percent of revenues and 1 firm (0.8 percent) will incur annual costs greater than 3 percent. The Final Pharmaceutical Industry Effluent Guidelines are thus considered a Category 1 rule. Category 1 rules may be certified as having no significant impact on a substantial number of small entities without performing a FRFA. To further support this finding, however, EPA follows with a FRFA.

EPA has selected facility closures and firm failures as identifying measures of significant impact in this FRFA. One facility owned by a multifacility firm will close (although only if MACT standards costs are included), one single-facility firm will fail and close, two single-facility firms will fail but will probably not close (i.e., they will lose their financial independence), and one multifacility firm will fail or must sell (but not close) one or more of its facilities. All of the firms associated with these impacts are small firms. Given that 76 percent of all affected firms are small, this result is not disproportionate. If exact proportionality of impacts were to have occurred, we could expect out of five significantly affected firms that four would have been small. The difference between four significantly affected small firms out of five total affected firms (large or small) and five significantly affected small firms out of five total affected firms is minimal.

1.10 COSTS AND BENEFITS OF THE FINAL PHARMACEUTICAL INDUSTRY EFFLUENT GUIDELINES AND THE MACT STANDARDS RULE

EPA has undertaken this analysis to address the requirements of Executive Order 12866 and the Unfunded Mandates Reform Act. Agencies are required to address the costs and benefits of a regulation under both of these if the annual cost of a rule on either private industry or governments is expected to be $100 million or more. Although each rule independently will not be close to $100 million in annual costs, the combined costs of the two rules is greater than $100 million when all social costs are considered and when costs are inflated to current-year dollars.

1.10.1 Social Costs

The costs of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule are presented in Section 1.4 of this executive summary. These costs, however, are only the costs to industry. The tax savings realized by industry are, in fact, still costs borne by the state and federal governments as forgone income. Thus the total social cost (costs to all segments of the economy) is understated by the amount of these tax shields. Other costs not included in the preceding estimate are costs to administer the regulations (permitting costs) and costs associated with unemployment (administration costs only; unemployment benefits are transfers, and willingness to pay to avoid unemployment are assumed captured in the compliance

costs of facilities that are projected to close postcompliance). These costs, along with the pretax annual costs of compliance are the major components of social costs.

EPA estimates the pretax costs of compliance using the same cost annualization model used to estimate posttax costs of compliance with Final Pharmaceutical Industry Effluent Guidelines. The model outputs both sets of costs. Table 1-4 presents the pretax costs of compliance for the Final Pharmaceutical Effluent Guidelines and the MACT standards rule (as computed by OAQPS), separately and together. As the table shows, the social (pretax) cost of compliance for the subcategories under the effluent guidelines range from $1.1 million to $36.1 million annually ($1990) ($1.4 million to $44.5 million, $1997), depending on subcategory. The selected options have an annualized pretax cost of $49.4 million ($1990) ($60.8 million, $1997).

EPA assumes that all direct dischargers are currently covered by a permit and these facilities will not be associated with incremental costs to permit. Indirect dischargers are assumed to require incremental effort to permit.

EPA estimates that the average annualized cost of $206,585 ($1990) ($254,345, $1997) is the social cost of administering the rule. Even with the conservative assumptions used in the analysis (i.e., that all permitting costs are incremental to current costs of administering indirect dischargers, even though most have some level of permits in place, and that permits will be costlier mass-based not concentration-based permits), administrative costs are less than 1 percent of the estimated compliance costs.

Finally, EPA estimates the costs of administering unemployment, based on an estimated $100 per laid-off worker and the projected national-level impacts on employment, including indirect and induced employment effects (which overstates actual employment losses, because these estimates are hours lost, not necessarily jobs lost). EPA estimates that maximum unemployment benefits administration costs will be $10,730 ($13,210, $1997) annually over all selected options.

Table 1-4 also presents the total social costs associated with each of the selected options. These costs range from $1.1 million to $36.2 million annually ($1990) ($1.4 million to $44.6 million, $1997), depending on the subcategory. The selected options are associated with annual total social costs of $49.6 million ($61.0 million, $1997).

Table 1-4

Social Costs of Compliance
(thousands of dollars)

Regulatory Option	Compliance Costs		Administrative Costs		Unemployment Benefits Administration Costs		Total Costs	
	$1990	**$1997**	**$1990**	**$1997**	**$1990**	**$1997**	**$1990**	**$1997**
BAT-A/C (with BPT)	$4,942.59	$6,085.26	$0.00	$0.00	$1.07	$1.32	$4,943.66	$6,086.59
BPT-B/D only	$1,121.23	$1,380.45	$0.00	$0.00	$0.24	$0.30	$1,121.48	$1,380.75
PSES-A/C	$36,131.97	$44,485.32	$76.02	$93.59	$7.86	$9.67	$36,215.84	$44,588.58
PSES-B/D	$7,166.66	$8,823.52	$130.57	$160.75	$1.56	$1.92	$7,298.78	$8,986.19
Total Selected Options	$49,362.44	$60,774.54	$206.59	$254.35	$10.73	$13.21	$49,579.76	$61,042.10
Total MACT, efluent guidelines facilities	$40,325.06	$49,647.81	NA *	NA *	$8.77	$10.80	$40,333.83	$49,658.60
Total MACT, all facilities	$47,446.95	$58,416.21	NA *	NA *	$10.32	$12.71	$47,457.27	$58,428.92
Total MACT, effluent guidelines + Selected Options	$89,687.50	$110,422.35	$206.59	$254.35	$19.50	$24.01	$89,913.59	$110,700.71
Total MACT, all facilities + Selected Options	$96,809.39	$119,190.76	$206.59	$254.35	$21.06	$25.92	$97,037.03	$119,471.03

* Administrative costs were not calculated for MACT but are expected to be small relative to the total costs of the two rules combined. Unemployment benefits administration costs were calculated using net FTE loss from Table 7-9.

1.10.2 Pollutant Reductions

The selected options are associated with postcompliance removals of 16.2 million pounds and 373,198 pound equivalents (pounds weighted by toxicity) from waters of the U.S. Note that these removals do not include the air removals associated with the MACT standards rule. These removals amount to an additional 48 million pounds.

1.10.3 Benefits of the Final Pharmaceutical Industry Effluent Guidelines

The benefit categories considered in this assessment of the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are identified below. Specifically, this assessment addresses the following:

- Human health and agricultural benefits due to reductions in emissions to air of ozone precursors (i.e., reductions in volatile organic compounds [VOC] emissions)
- Human health benefits due to reductions in excess cancer risk
- Ecological and recreational benefits (environmental) due to improved water quality, including intrinsic benefits
- Benefits from reductions in interference and passthrough problems, improvements in worker health, and reductions in analytical costs at POTWs
- Human health benefits due to reductions in systemic and other risks, such as risk of developmental effects or individual organ toxicity

For the first three benefit categories, sufficient information is available to monetize the benefits of the final rules. The dollar magnitude of the benefits for the other two benefit categories cannot be quantified. The methodology and data used in the estimate of all benefits, as well as the limitations, are described in detail in EPA's *Environmental Assessment of the Final Industry Guidelines for the Pharmaceutical Manufacturing Industry* (1998).

As shown in Table 1-5, the estimated annual monetized benefits resulting from the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions control portion of the MACT

Table 1-5

Total Costs and Benefits of the Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule
(thousands of dollars)

	Total Social Cost or Benefit Effluent Guidelines		Total Social Cost or Benefit MACT Standards Rule		Total Social Cost or Benefit Effluent Guidelines + MACT Standards Rule	
Type of Benefit	**$1990**	**$1997**	**$1990**	**$1997**	**$1990**	**$1997**
Compliance Costs	$49,362	$60,775	$47,447	$58,416	$96,809	$119,191
Administrative Costs	$207	$254	unquantified *	unquantified	$207	$254
Unemployment Administrative Costs	$11	$13	$10	$13	$21	$26
Total Social Costs	$49,580	$61,042	$47,457	$58,429	$97,037	$119,471
Human Health Benefits **	$123 - $9,040	$151 - $11,130	$3,150 - $54,600	$3,878- $67,223	$3,273 - $63,640	$4,030 - $78,353
Recreational Benefits	$419 - $1,495	$516 - $1,841	unquantified	unquantified	$419 - $1,495	$516 - $1,841
Nonuse Benefits	$210 - $748	$259 - $921	unquantified	unquantified	$210 - $748	$259 - $921
POTW Benefits +	unquantified	unquantified	unquantified	unquantified	unquantified	unquantified
Total Benefits ++	**$752 - $11,300**	**$926 - $13,912**	**$3,150 - $54,600**	**$3,878 - $67,223**	**$3,902 - $65,900**	**$4,804 - $81,135**

* Administrative costs were not calculated for the MACT standards rule but are expected to be small relative to the total costs of the two rules combined.
** Includes ozone reductions and cancer reductions.
+ Data are not available to monetize this benefit.
++ This range includes $285,000 to $1.0 million ($1990) ($340,000 to $1.2 million, $1997) of the environmental benefits that cannot be differentiated between the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions portion of the MACT standards rule. The total benefits numbers differ slightly from those presented in the preamble due to rounding of the benefits to two significant digits in the preamble.

standards rule will range from $0.7 million to $11.3 million ($1990) ($0.9 million to $13.9 million, $1997). This range includes $285,000 to $1.0 million ($340,000 to $1.2 million, $1997) of the environmental benefits that cannot be differentiated between the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions control portion of the MACT standards rule. The annual monetized benefits resulting solely from the MACT standards rule are estimated to range from $3.2 million to $54.6 million ($1990) ($3.9 milion to $66.9 million, $1997), for a total over both rules of $3.9 million to $65.9 million ($1990) ($4.8 million to $80.8 million, $1997) annually. The largest benefit category is human health benefits, with about 90 percent of the total dollar value of benefits under the combined rules. Table 1-5 summarizes these benefits, by category. The range reflects the uncertainty in evaluating the effects of the final rules and in placing a dollar value on these effects. These monetized benefits ranges do not reflect many of the benefit categories expected to result under the final rules, including reduced systemic human health hazards; improved POTW operations/conditions; and improved worker health at POTWs. Therefore, the reported benefit estimate understates the total benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

Table 1-5 also presents the social costs of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule. Only the costs and benefits of the selected effluent guidelines options are presented here.

As the table shows, the Final Pharmaceutical Industry Effluent Guidelines are associated with costs totaling $49.6 million ($61.0 million, $1997), with benefits totaling $0.7 million to $11.3 million ($1990) ($0.9 million to $13.9 million, $1997). With costs and benefits of the MACT standards rule included, costs of both rules are $102.2 million ($1990) ($125.8 million, $1997) and benefits of both rules range from $3.9 million to $65.9 million ($1990) ($4.8 million to $81.1 million, $1997).